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10/769,405	01/30/2004	William Ryan Overall	STAN-345	8227

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EXAMINER

NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/769,405

Applicant(s)

OVERALL ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 21-41 and 62-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 42-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/17/04, 7/5/05, 8/31/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Invention 1 in the reply filed on 10/25/2006 is acknowledged. The traversal is on the ground(s) that examination of the entire application would not constitute a burden. This is not found persuasive because the inventions are distinct as claimed, wherein the apparatus can perform a materially different method such as alerting the user when certain circumstances are present, as evidenced by the omission of said step from said method claims. Because such claims are distinct, a different and separate search is necessitated which constitutes burden.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 21-41 and 62-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/25/2006.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged, namely, priority to provisional application #60443938, filed on 1/31/2003.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 8/17/2004, 7/5/2005, and 8/31/2006 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 1-8, 14, 17-20, 42-54, and 57-61** are rejected under 35 U.S.C. 102(e) as being anticipated by Sheldon et al (US Pub No. 20030158492).

8. In regards to **Claim 1**, Sheldon et al disclose a system for monitoring cardiac function in a human patient, the system comprising (a) an intracorporal motion sensor (¶0040) positioned at

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the apex of the heart (§0095), which is in operable connection with (b) a motion analysis element comprising analog-to-digital converter circuitry (§0064); central processing unit (§0062) for processing signals from said motion sensor; memory (§0065) for storing at least one baseline motion parameter; and an element for transmitting information to an alarm system (§0047).

9. In regards to **Claim 2**, Sheldon et al disclose a programmer for analyzing and setting motion parameters (§0064-0065).

10. In regards to **Claim 3**, Sheldon et al disclose one or more non-motion sensors, i.e pressure sensors (abst).

11. In regards to **Claim 4**, Sheldon et al disclose a motion sensor capable of being placed at other than the cardiac apex.

12. In regard to **Claims 5 and 49**, Sheldon et al disclose a reference sensor (§0048-0049).

13. In regard to **Claims 6 and 50**, Sheldon et al disclose said motion sensor is implanted at said apex of the heart for sensing apical motion (§0095).

14. In regard to **Claims 7 and 51**, Sheldon et al disclose said motion sensor is implanted endocardially at the right-ventricular apex, the epicardial apex, or an apical cardiac vein (§0095).

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15. In regard to **Claims 8 and 54**, Sheldon et al disclose said operable connection between said motion sensor and said motion analysis element comprises an electrical lead, best seen in Figures 1-2.

16. In regards to **Claim 14**, Sheldon et al disclose an alarm capable of warning a preset threshold for a motion parameter has been exceeded, wherein the indication of ischemia is determined when a threshold for a motion parameter associated with said motion sensor is exceeded (§0073).

17. In regard to **Claims 17 and 43**, Sheldon et al disclose said motion sensor is an accelerometer.

18. In regard to **Claims 18 and 44**, Sheldon et al disclose said motion sensor is a MEMS strain gyro (§0052).

19. In regards to **Claim 19**, Sheldon et al disclose said motion analysis element is configured to receive data input from one or more of a magnet sensor; timing circuit; and telemetry subsystem (§0065).

20. In regards to **Claim 20**, Sheldon et al disclose said motion analysis element is configured to transmit data output to one or more of a pacemaker circuit; defibrillator circuit, and timing circuit (§0071).

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21. In regard to **Claims 42**, Sheldon et al disclose a system for monitoring cardiac function in a human patient, the system comprising:

At least one motion sensor (abst) adapted for positioning at the apex of the heart (§0095) and for sensing the overall movement of the heart;

A motion analysis element (§0061) in operable communication with the at least one motion sensor, the motion analysis element adapted for receiving signals representative of the overall movement of the heart from the at least motion sensor and for processing the received signals, wherein said signals are related to at least one predetermined baseline value of the movement of the heart.

22. In regards to **Claim 45**, Sheldon et al disclose the motion sensor is configured to sense motion within at least one directional axis (§0057).

23. In regard to **Claims 46-47**, Sheldon et al disclose the motion sensor configured to sense motion in only one directional axis (§0096), said directional axis capable of being the anterior-posterior direction relative to the heart.

24. In regards to **Claim 48**, Sheldon et al disclose the system capable of comprising a single motion sensor.

25. In regards to **Claim 52**, Sheldon et al disclose the at least one motion sensor is configured to interpret the processed signal as representative of an ischemic condition of the heart (abst).

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26. In regards to **Claim 53**, Sheldon et al disclose the ischemic condition of the heart is a location of an ischemic area, a location of an occluded coronary artery or the degree of the ischemic condition (§0072).

27. In regards to **Claim 57**, Sheldon et al disclose the motion analysis element is further configured to transmit an alarm signal when the processed signal is determined to be outside a predetermined threshold range as explained above.

28. In regards to **Claim 58**, Sheldon et al disclose the motion analysis element is configured to provide therapeutic treatment to the heart when the processed signal is determined to be outside a predetermined threshold range, wherein the indication of ischemia is confirmed when the processed signal is outside a predetermined threshold range (§0038).

29. In regards to **Claim 59**, Sheldon et al disclose the therapeutic treatment comprises the delivery of pacing signals (§0059).

30. In regards to **Claim 60**, Sheldon et al disclose the therapeutic treatment comprises the delivery of an agent (§0038).

31. In regards to **Claim 61**, Sheldon et al disclose an electrocardiogram means (§0042).

Claim Rejections - 35 USC § 103

32. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

33. **Claims 9-10 and 15-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al.

34. In regards to **Claim 9**, Sheldon et al disclose an operable connection between the motion sensor and the motion analysis element as well as the use of telemetry (§0065) but do not explicitly teach said operable connection comprises a telemetry connection for ease of data transfer. However, it would have been obvious to one of ordinary skill in the art to modify the connection between the motion sensor and the motion analysis element of Sheldon et al to be a telemetry connection to enhance the ease of data transfer.

35. In regards to **Claim 10**, Sheldon et al disclose said motion analysis element is an external device (§0065).

36. In regards to **Claim 15**, Sheldon et al disclose communication between said programmer and said motion analysis element but do not explicitly teach using two-way wireless communication. Sheldon et al do disclose the use of telemetry for ease of data transfer. Therefore, it would have been obvious to one of ordinary skill in the art to modify the

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communication between said programmer and said motion analysis element of Sheldon et al to be two-way wireless communication to promote ease of data transfer.

37. In regards to **Claim 16**, Sheldon et al disclose said programmer comprises software for analysis of motion sensing data (§0064).

38. **Claims 11-13, and 55-56** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al in view of Mouchawar et al (US Pat No. 6009349).

39. In regards to **Claim 11**, Sheldon et al disclose the invention above but do not disclose using a catheter for delivery of said system. Mouchawar et al teach that a catheter may be used to introduce various devices into the body, as is also commonly known in the art. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Sheldon et al to include a catheter for delivery of said system as an effective method to do so.

40. In regard to **Claims 12-13 and 55-56**, Sheldon et al disclose the invention above but do not explicitly disclose said motion analysis element substantially integrated with another intracorporeal device. Mouchawar et al disclose that an analogous invention comprising a motion analysis element may be substantially integrated into another intracorporeal device such as a pacemaker or defibrillator (Col.8: 62-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substantially integrate the motion analysis element of Sheldon et al into another intracorporeal device such as a pacemaker or a

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defibrillator to produce an enhanced device capable of multiple functions without having to implant an additional device into the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
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